



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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JUN 26 2000

Jeremy Rifkin
The Foundation on Economic Trends
1660 L Street, NW, Suite 216
Washington, DC 20036

Re: Docket Nos. 94P-0319/CP1 & 94P-0320/CP1

Dear Mr. Rifkin:

According to the records of FDA's Dockets Management Branch, the two citizen petitions referenced above have not been formally resolved. Both petitions are dated August 30, 1994. The first petition requests that FDA (1) broaden the Agency's investigation of human growth hormone (hGH) to include marketing activities with ties to hospitals; (2) determine whether any such activities constitute deceptive marketing practices; and (3) ascertain whether doctors or hospitals involved with such practices improperly used their institutional affiliation to market hGH. The second petition requests that FDA (4) investigate black market sales of hGH; (5) examine the sales records of manufacturers and distributors to see if large amounts of hGH are being diverted to the black market; and (6) impose harsh penalties for violations of applicable Agency regulations.

Your petitions have been identified as among those submitted more than five years ago that, as a result of subsequent events, no longer appear to present a current issue. Our investigations into the specific events that preceded and prompted your petitions are complete, and so we believe it is appropriate to close the dockets for these petitions. A review of the dockets indicates that they have been inactive for many years. Our response, therefore, will be very brief.

With respect to aspects of the first, second, third, and sixth requests listed above, your requests have been substantially granted by the outcomes of various investigations and prosecutions. In April of 1999, it was announced that Genentech will pay \$50 million in fines for its promotion practices of hGH between 1985 and 1994. Also, in a case involving the Department of Health and Human Services (although not the FDA), it should be noted that Caremark International, Inc., agreed in 1995 to pay \$161 million in fines for its alleged illegal payments to doctors enrolling patients for hGH treatment. Numerous criminal prosecutions of individuals also resulted from these cases.

94P-0319

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Docket Nos. 94P-0319/CP1 & 94P-0320/CP1

Regarding your fourth and fifth requests as listed above, we must repeat the statement given in our March 5, 1995, interim response to your petitions, i.e., we cannot provide details of any ongoing investigations. Also, as indicated on pages 5-6 of your petition dated August 5, 1994 submitted to the Drug Enforcement Administration (DEA), you are aware that the DEA is authorized under 21 U.S.C. 333(e) to investigate the "prohibited distribution" of hGH.

FDA has not ceased investigating hGH. For the foreseeable future, we will continue to monitor the marketing and distribution of hGH very carefully. FDA shares your concern about the misuse and abuse of hGH, but we now consider your petitions to have been resolved.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Dennis E. Baker", with a long, sweeping horizontal line extending to the right.

Dennis E. Baker
Associate Commissioner
for Regulatory Affairs